

Phase I trial HMR code: 23-006

Submission date 26/01/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/02/2024	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/02/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Contact information

Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1008812

Protocol serial number
IRAS 1008812, HMR code: 23-006

Study information

Scientific Title
Phase I trial HMR code: 23-006 [The full scientific title will be published within 30 months after the end of the trial]

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 21/12/2023, Harrow Research Ethics Committee (2 Redman Place, Stratford , London, E20 1JQ , United Kingdom; +44 (0)207 1048154; harrow.rec@hra.nhs.uk), ref: 23/LO /0809
2. approved 04/01/2024, MHRA (10 South Colonnade, Canary Wharf, London , E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 04854/0225/001-0001

Study design

First-in-human safety, pharmacokinetics, and pharmacodynamics trial in up to 168 healthy volunteers

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

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Key secondary outcome(s)

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Completion date

08/11/2025

Eligibility**Key inclusion criteria**

Healthy human volunteer

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

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Date of first enrolment

13/02/2024

Date of final enrolment

08/08/2025

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

HMR

Cumberland Avenue

Park Royal

London

United Kingdom

NW10 7EW

Sponsor information**Organisation**

Gedeon Richter (Hungary)

ROR

<https://ror.org/0033rtn64>

Funder(s)

Funder type

Industry

Funder Name

Gedeon Richter

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Hungary

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results of non-therapeutic clinical trials.

IPD sharing plan summary

Not expected to be made available